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09/575,638	05/22/2000	Lisa Anne Laffend	CR9715 US DIV1	1504

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT PAPER NUMBER

1653

DATE MAILED: 08/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/575,638

Applicant(s)

LAFFEND ET AL.

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 6, 31 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 6, 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The amendment of 5/2003 is acknowledged. Claims 1, 3-5, 7-19 and 32-33 have been cancelled, rendering any rejections of these claims as moot. Claims 2, 6, and 31 remain under consideration, while claim 34 remains withdrawn. In order to determine whether a typographical error occurred, the Examiner reviewed earlier documents. It was noted that the only statement regarding cancellation of claim 34 was in the remarks section of the non-entered paper of 11/2002,. In the final line of page 3 of the 5/2003 amendment, only claims 1, 3-5, 7-19 and 32-33 are cancelled. Applicants are reminded that claim 34 remains pending.

Specification

The objection to the disclosure because of incomplete deposit information is withdrawn, based upon the amendment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 2, 6 and 31 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6025184.

Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to use the claimed microorganism of the patent in a process of making propanediol since the exogenous genes enable the host to make propanediol.

With respect to claim 31, it is obvious to use the exogenous gene of the patented microorganism to transform yeast, as yeast are a common source for industrial production of chemical compounds.

It is stated on page 4 of the response that a terminal disclaimer has been provided. No such document could be found in the application; indeed, the transmittal letter of 5/2003 does not indicate such an enclosure.

The rejection of claim 6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-16 of U.S. Patent No. 5,686,276 in view of Daniel *et al.*(1992), in light of Daniel *et al.* (1995), is withdrawn, based upon the amendment.

Claims 2 and 6 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-19,21, 25, 28 and 30 of claims 1-10 of U.S. Patent No. 5821092. Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ merely in scope. The independent claims of the instant application are directed to a process using microorganisms having a dehydratase

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gene, whereas those of the copending application are drawn solely to microorganisms transformed with a dehydratase gene. It is obvious to use the claimed microorganism of the patent .in a process of making propanediol since the exogenous genes enable the host to make propanediol. It is unclear whether the statement on page 4 of the response regarding submission of a terminal disclaimer is intended to apply to this rejection.

Claims 2, 6 and 31 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,633,362.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ merely in scope and are drawn to genes on the same cosmid and transformed organisms containing genes of the cosmid. With respect to claims 2 and 6, it is obvious to use the claimed microorganism of the patent .in a process of making propanediol since the exogenous genes enable the host to make propanediol. It is unclear whether the statement on page 4 of the response regarding submission of a terminal disclaimer is intended to apply to this rejection.

Claims 2, 6 and 31 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,633,362.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ merely in scope. It is unclear whether the statement on page 4 of the response regarding submission of a terminal disclaimer is intended to apply to this rejection.

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Claims 2, 6 and 31 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6013494.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application states at least one exogenous gene encoding a glycerol dehydratase be used, whereas the claims of the patent state that at least one four specifically recited genes including a dehydratase gene is used. It is unclear whether the statement on page 4 of the response regarding submission of a terminal disclaimer is intended to apply to this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 2, 6 and 31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of generating 1, 3, propane diol with microorganisms transformed with the *Klebsiella pneumoniae dhaB* gene, does not reasonably provide enablement for production of 1, 3 propane diol by the recited microorganisms transformed with any diol dehydratase gene from any other organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The instant application shows the production of 1, 3, propane diol from organisms transformed with the glycerol dehydratase gene of *Klebsiella pneumoniae*, but does not address how to purify or isolate any other dehydratase genes from any other organism. No teaching is given regarding sequence similarity either between *dhaB* genes of different organisms or between dehydratase genes in general. Furthermore, the specification fails to teach any other dehydratase that can be used to generate 1, 3, propane diol; the diol dehydrase of Tobimatsu *et al*, for example, catalyzes the conversion of 1, 2 diols to the corresponding aldehydes and is not known to produce 1, 3, propanediol. The specification does not teach how one may use such an enzyme in the claimed process. It is deemed that the scope of the claims is much broader than the enablement provided by the specification and that undue experimentation would be involved in obtaining other dehydratase genes with which to practice the claimed invention.

Applicants have not addressed this rejection.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn, based upon the amendment.

Claim Rejections - 35 USC § 102

The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Daniel *et al.* is withdrawn, based upon the amendment.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

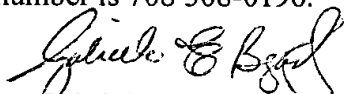
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.


Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

August 8, 2003